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10/526,285	03/02/2005	Nitin Bhalachandra Dharmadhikari	006420.00004	4683

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,285	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18,23 and 27* is/are pending in the application.

4a) Of the above claim(s) *29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-18,23 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 03/20/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention of claim 29 and the invention originally claimed are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case : the originally claimed product can be used as a muscle relaxant.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejoinder Practice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The amendment filed 03/20/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a new definition for "enhanced bioavailability" has been added to the specification. There is no support for the new definition for the phrase found in the specification as originally filed. The phrase has been newly defined in the amended specification submitted on 03/20/2008 as follows:

> "The term "enhanced bioavailability" as referred to herein means that in comparative bioavailability study wherein Skelaxin® tablet (New Drug Application No. 13-217) as reference product and the pharmaceutical composition of the present invention having an amount of metaxalone equivalent to that in the reference Skelaxin® tablet are given to human volunteers under fasted conditions (on an empty stomach), the extent of absorption as measured by the ratio of area under the plasma concentration versus time curve for the test versus the reference product is greater than 120% and the rate of absorption is faster as measured by the mean time (mean Tmax) taken to reach the peak plasma concentration which is less than for the reference product."

The phrase was initially described as follows:

> "(¶ [0005] Enhanced oral bioavailability of drug substance is known to increase both onset of action and therapeutic efficacy of the drug)."

> "(¶ [0022]) Bioavailability referred to herein is rate and extent to which the active drug ingredient, metaxalone, is absorbed into the systemic circulation from the pharmaceutical composition of the present invention."

This does not fully support the definition as amended in the response filed on 03/20/2008.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7-18, 23 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. (USP 5,145,684) in view of Scaife et al. (USP 6,407,128). This rejection is maintained.

Claims 1, 4-7, 15-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (USP 4,344,934) in view of Scaife et al (USP 6,407,128). This rejection is maintained.

Applicant argues that the combination of references does not suggest an increase in both the rate and extent of absorption of metaxalone on an "empty stomach". Applicant alleges the result of enhancement of both rate and extent of absorption is unexpected when taken on an empty stomach. Applicant argues that the example in the secondary reference produced contrary results (decrease in rate of absorption).

However, the present claims do not require metaxalone to have an "increased rate of absorption". They only require the bioavailability to be "enhanced". The term "enhance bioavailability" reasonably encompasses a rate of absorption that is either decreased or increased depending on what is desired. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "an increase in both rate and

extent of absorption") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, even if the limitation "an increase in both rate and extent of absorption" is recited in the claim it would have still been obvious to the skilled artisan because there is some predictability in accomplishing the method.

Applicant has argued specifically against the secondary reference's disclosure in Table II b at col. 5 of this reference, alleging that the reference discloses results contrary to an "increase in rate of absorption", a limitation that is not required in the claims.

The reference discloses that the Tmax of metaxalone is increased when it is taken on an empty stomach when taken with food. The Examiner does not agree with Applicants conclusion that this inherently means the rate of absorption is, therefore, decreased; the disagreement is because Tmax is also dependent on **excretion** from the body where there is an equilibrium between absorption and excretion. Even if this did mean that the rate of absorption is inherently decreased, *in arguendo*, it still does not present any evidence that is contrary to what is allegedly claimed. The claims, according to Applicant, require a composition that has an increased rate and extent of absorption as compared to the conventional Skelaxin® composition when given on an empty stomach. The primary reference is relied upon to show how bioavailability is generally enhanced for drugs that one desires to have enhanced oral bioavailability for.

The combination of the references makes obvious the claims whether it is on an empty stomach or not. The suggested composition would reasonably be expected to have an enhanced bioavailability as compared to the conventional composition because the primary reference discloses methods to generally increase the bioavailability of drugs.

The Applicant has provided references to show there is some unpredictability within the art of increasing bioavailability. Obviousness *does not require absolute predictability*, however, at least some degree of predictability is required. See MPEP 2143.02. The Examiner submits that the combination of the references, at least, meets the requirement that there is *some degree* of predictability after reviewing the prior art as a whole and with the understanding that many factors effect absorption.

Applicant alleges that important factors concerning nonobviousness are overlooked in the prior Office Action: the unexpected result of the present invention is enhanced bioavailability even when the composition is administered to a patient on an empty stomach. However, these alleged "unexpected results" have been sufficiently considered and are obvious for reason cited in the prior Office Action.

As for the alleged unmet need for such a composition, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

As for Applicant's assertion that prior arguments have not been responded to, those arguments have been rendered moot because new rejections have been made since those arguments were submitted.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, in addition to the reasonable expectation of successfully enhancing bioavailability of metaxalone, it would have also been obvious to make a composition having enhanced bioavailability without requiring the need to eat food and, therefore, making it easier to properly administer the drug.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612